

**REMARKS**

Reconsideration of the application is respectfully requested.

Claims 27-78 are pending. Claims 48-54, 62-66 and 76-78 are free of prior art and will be allowable upon filing of terminal disclaimers.

**Rejection under 35 USC Section 102**

Claims 27-47, 55-61 and 67-75 are rejected as being anticipated by US Patent No. 5,211,944 to Tempesta [hereinafter "Tempesta"]. Applicants respectfully traverse the rejection.

The Examiner states that "Tempesta ... teaches the use of proanthocyanidins, which broadly embraces and includes the procyanidins" (Office Action mailed June 21, 2005, page 5) (emphasis added by Applicants). The Examiner further states that the paragraph bridging cols. 1-2 of Tempesta patent teaches "the pharmaceutical use" of procyanidins (Advisory Action mailed October 31, 2005).

Applicants do not disagree that the large class of proanthocyanidins "embraces and includes" procyanidins. In their response filed April 22, 2005, Applicants have explained in detail the differences in terminology between procyanidins and proanthocyanidins, and have explained that procyanidins are one of the many subgroups of proanthocyanidins. In other words, procyanidins represent a subgenus of proanthocyanidin compounds.

According to the MPEP, Section 2131.02 (enclosed), "[w]hen the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g. select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated."

Application of the above law requires review of Tempesta's disclosure. Tempesta describes that proanthocyanidins having the formulae I-IV are "useful for treating respiratory viral infections" (see col. 6, line 22-col. 9, line 1). However, with respect to this utility, Tempesta does not specifically name procyanidin oligomers recited in the rejected Applicants' claims. In fact, in order to arrive at procyanidins recited in the rejected claims, one must:

- (i) select "a" in formulae I-III, and "x" in formula IV to equal 2 (generic formulae of Tempesta provide for 1-3 OH groups);

- (ii) select locations of "a" in formulae I-III, and "x" in formula IV, at positions C5 and C7 (Tempesta's generic formulae provide for OH at any position C5-C8);
- (iii) select "x" in formulae I-III, and "z" in formula IV to equal 1 (generic formulae of Tempesta provide for 0 or 1)
- (iv) select locations of "x" in formulae I-III, and "z" in formula IV, at position C3 (Tempesta's generic formulae provide for OH at any position C3-C4);
- (v) select "b" in formulae I-III, and "y" in formula IV to equal 2 (generic formulae of Tempesta provide for 1-3 OH groups);
- (vi) select locations of "b" in formulae I-III, and "y" in formula IV, at positions C3' and C4' (Tempesta's generic formulae provide for OH at any position C2'-C6');
- (vii) repeat selections (i)-(vi) for each monomeric unit of Tempesta's generic formulae (up to 30 units).

Finally, the formulae of Tempesta encompass a huge number of compounds, out of which procyanidins are a small subset.

Because: (i) procyanidins are not named by Tempesta as being useful as anti-viral agents (or having any other utility); (ii) to arrive at procyanidins, one must select various substituents from a list of alternative substituents on generic structural formulae of Tempesta; and (iii) generic structural formulae of Tempesta encompass a vast if not infinite number of compounds (see attached MPEP's reference to *In re Pettering*), MPEP, Section 2131.02 prohibits finding of anticipation.

The Examiner points out to the statement in Background of Tempesta's patent (par. bridging cols. 1 and 2) where Tempesta states, *inter alia*, that compounds having chains of 5; 7, 3', 4' tetrahydroxy flavonoid 3-ol units (see formula) belong to the class of compounds known as proanthocyanidins. However, there is no statement in that paragraph (or the entire Section 2.2, col. 1, line 62-col. 3, line 45) that procyanidins recited in rejected Applicants' claims have any biological activities. Applicants do not claim procyanidin compounds *per se*, their claims are directed to pharmaceutical compositions. Pharmaceutical use is not disclosed in the paragraph referenced by the Examiner.

In view of the above remarks and the attached MPEP, Section 2131.02 withdrawal of the rejection is respectfully requested.

**Double Patenting Rejection**

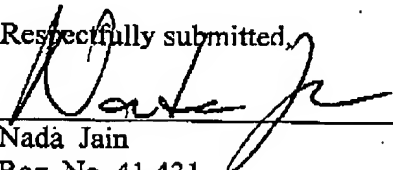
Further to the Terminal Disclaimer filed on April 22, 2005 over U.S. Pat. No. 6,479,539; Applicants will file terminal disclaimers over the patents cited by the Examiner upon finding of otherwise allowable subject matter.

**CONCLUSION**

In view of the above remarks, Applicants believe that the application is now in condition for allowance. A notice to that effect is respectfully requested.

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## 2131.02

## MANUAL OF PATENT EXAMINING PROCEDURE

requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration" . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See MPEP § 2112 - § 2112.02 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

### 2131.02 Genus-Species Situations

#### A SPECIES WILL ANTICIPATE A CLAIM TO A GENUS

"A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989)

(Gosteli claimed a genus of 21 specific chemical species of bicyclic thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date.).

#### A REFERENCE THAT CLEARLY NAMES THE CLAIMED SPECIES ANTICIPATES THE CLAIM NO MATTER HOW MANY OTHER SPECIES ARE NAMED

A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the *Merck Index*, saying that "the tenth edition of the *Merck Index* lists ten thousand compounds. In our view, each and every one of those compounds is 'described' as that term is used in 35 U.S.C. § 102(a), in that publication."). *Id.* at 1718. See also *In re Sivaramakrishnan*, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982) (The claims were directed to polycarbonate containing cadmium laurate as an additive. The court upheld the Board's finding that a reference specifically naming cadmium laurate as an additive amongst a list of many suitable salts in polycarbonate resin anticipated the claims. The applicant had argued that cadmium laurate was only disclosed as representative of the salts and was expected to have the same properties as the other salts listed while, as shown in the application, cadmium laurate had unexpected properties. The court held that it did not matter that the salt was not disclosed as being preferred, the reference still anticipated the claims and because the claim was anticipated, the unexpected properties were immaterial.).

## PATENTABILITY

2131.03

**A GENERIC CHEMICAL FORMULA WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THE FORMULA WHEN THE SPECIES CAN BE "AT ONCE ENVISAGED" FROM THE FORMULA**

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

In *In re Petering*, the prior art disclosed a generic chemical formula "wherein X, Y, Z, P, and R- represent either hydrogen or alkyl radicals, R a side chain containing an OH group." The court held that this formula, without more, could not anticipate a claim to 7-methyl-9-[d, l-ribityl]-isoalloxazine because the generic formula encompassed a vast number and perhaps even an infinite number of compounds. However, the reference also disclosed preferred substituents for X, Y, Z, R, and R' as follows: where X, P, and R' are hydrogen, where Y and Z may be hydrogen or methyl, and where R is one of eight specific isoalloxazines. The court determined that this more limited generic class consisted of about 20 compounds. The limited number of compounds covered by the preferred formula in combination with the fact that the number of substituents was low at each site, the ring positions were limited, and there was a large unchanging structural nucleus, resulted in a finding that the reference sufficiently described "each of the various permutations here involved as fully as if he had drawn each structural formula or had written each name." The claimed compound was 1 of these

20 compounds. Therefore, the reference "described" the claimed compound and the reference anticipated the claims.

In *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound. The broad generic formula seemed to describe an infinite number of compounds but claim 1 was limited to a structure with only one variable substituent R. This substituent was limited to low alkyl radicals. One of ordinary skill in the art would at once envisage the subject matter within claim 1 of the reference.).

Compare *In re Meyer*, 599 F.2d 1026, 202 USPQ 175 (CCPA 1979) (A reference disclosing "alkaline chlorine or bromine solution" embraces a large number of species and cannot be said to anticipate claims to "alkali metal hypochlorite."); *Akzo N.V. v. International Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986) (Claims to a process for making aramid fibers using a 98% solution of sulfuric acid were not anticipated by a reference which disclosed using sulfuric acid solution but which did not disclose using a 98% concentrated sulfuric acid solution.). See MPEP § 2144.08 for a discussion of obviousness in genus-species situations.

### 2131.03 Anticipation of Ranges [R-2]

#### 1. < A SPECIFIC EXAMPLE IN THE PRIOR ART WHICH IS WITHIN A CLAIMED RANGE ANTICIPATES THE RANGE

"[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art." *Titanium Metals Corp. v. Bunker*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original) (Claims to titanium (Ti) alloy with 0.6-0.9% nickel (Ni) and 0.2-0.4% molybdenum (Mo) were held anticipated by a graph in a Russian article on Ti-Mo-Ni alloys because the graph contained an actual data point corresponding to a Ti alloy